



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Hakan LOMRYD, et al.

Title:

PHARMACEUTICAL  
COMPOSITION AS SOLID  
DOSAGE FORM AND METHOD  
FOR MANUFACTURING  
THEREOF

Appl. No.: 10/626,857

Filing Date: 07/25/2003

Examiner: Carlos A. Azpuru

Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**FEE**

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 22, 2005

By Courtenay C. Brinckerhoff

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

JUL 22 2005 Date Submitted: July 22, 2005

(use as many sheets as necessary)

1 of 1

**Complete if Known**

<b>Application Number</b>	10/626,857
<b>Filing Date</b>	07/25/2003
<b>First Named Inventor</b>	Harkan LOMRYD et al.
<b>Group Art Unit</b>	Carlos A. Azpuru
<b>Examiner Name</b>	1615
<b>Attorney Docket Number</b>	052209-0105

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	2003/0091637	A1	Hans-Ulrich Petereit et al.	05/15/2003	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A2	EP	0 752 877	B1	Ferring B.V.	07/05/2000		
	A3	EP	0 710 122	B1	Ferring BV	12/12/2001		
	A4	EP	1 255 557	A1	Gebro Pharma GmbH	11/13/2002		
	A5	WO	95/18602		Alkermes Controlled Therapeutics Inc.	07/13/1995		
	A6	WO	03/094886	A2	Ferring BV	11/20/2003		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A7	"Pharmaceutical Dosage Forms: Tablets"; vol. 1, pp. 297-298, H.A. Lieberman et al., New York & Basel, 1989.	
	A8	"Pharmaceutical Dosage Forms: Parenteral Medications", vol. 3, pp. 27-29, H.A. Lieberman et al., New York & Basel, 1990.	
	A9	"Pharmaceutics – The Science of Dosage Form Design", pp. 625-627, M.E. AULTON et al., Edinburgh, London, Melbourne & New York, 1988.	
	A10	"Handbook of Pharmaceutical Excipients", Ed. A.H. Kibble, 3 <sup>rd</sup> Ed., American Pharmaceutical Association, USAS and Pharmaceutical Press UK 2000.	
	A11	N.A. ARMSTRONG; "Tabletting", Pharmaceutics – The Science of Dosage Form Design, pp. 647-668, 1988.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.